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10/519,093	04/11/2005	Udi Damari	26479U	6784

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,093	DAMARI ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-90* is/are pending in the application.

4a) Of the above claim(s) *89 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 75-90 are pending.

Claims 1-74 are cancelled.

Claims 89-90 are withdrawn as being directed to a non-elected invention.

Claims 75-88 have been examined.

Specification

Response to Arguments

Applicant's arguments, see remarks p 6, filed 15 May 2008, with respect to the objection to the specification as containing hyperlinks and trademarks have been fully considered. The objection to the specification has been withdrawn in view of the amendments to the specification to correct formalities.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 75-88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianaroli et al. (Human Reproduction, Vol. 15 No. 10, p 2241-2246, 2000), in view of Whisler et al. (Clinical Chemistry, Vol. 36, No9, p. 1587-1588, 1990).

The claims are directed to a method of controlling the processing of components involved in an *in vitro* fertilization (IVF) in which a matching set of two or more components are defined; each of the components is assigned a unique machine-readable identification mark; providing on each component the identification mark; reading the identification mark of a component to verify that the component belongs to the matching set. In some embodiments, the components that are marked are consists of holders, physician, embryos,

oocytes, spermatozoa. In some embodiments, the matching set includes an embryo and a recipient. In some embodiments, the identification mark assigned to components is different. In some embodiments, the matching set includes a sperm and an oocyte. In some embodiments, a matching set corresponds to a biological entity and a holder. In some embodiments, an entity is within a holder and the holder is labeled. In some embodiments, the identification marks assigned to the components are the same. In some embodiments, the patient and their records are matched through the assignment of an identification mark. In some embodiments, the barcode is readable by scanning. In some embodiments, the identification mark is a barcode. In some embodiments, the identification mark is an image readable mark. In some embodiments, a label having the identification mark is affixed to a holder.

Gianaroli et al. shows a method for controlling the processing of components used in *in vitro* fertilization. Gianaroli et al. shows that a matching set of two or more components is defined and that the components are assigned a unique identification (p. 2243, col. 1, sect 4). Gianaroli et al. shows that unique identification mark is used to verify the components belong to the correct patients (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment the components that are marked are consists of holders, physician, embryos, oocytes, and spermatozoa (p. 2243, col. 1 -2244, col. 1). Gianaroli et al. shows in an embodiment, that the identification mark assigned to components is different (p. 2244, col. 1, sect. 7.2). Gianaroli et al. shows in an embodiment that the matched set is an embryo and a recipient (p. 2245, col. 1-2). Gianaroli et al. shows in an

embodiment that the matching set includes a sperm and an oocyte (p. 2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which an entity is within a holder and the holder is labeled, reading on the embodiments of at least an entity is within a holder, where the holder is labeled with identification mark and a matching set corresponding to a biological entity and a holder (p. 2245, col.2, sect. 12.6). Gianaroli et al. shows that the identification marks assigned to the components are the same (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which the patient and their records are matched through the assignment of an identification mark (p. 2241, col. 2 sect 2).

Gianaroli et al. does not show that the unique identification is machine-readable.

Whisler et al. shows use of machine-readable identification marks and shows the identification marks are used to control the automatic processing of medical specimens. Whisler et al. shows that the machine-readable identification mark is a barcode (p. 1588, col. 1). Whisler et al. shows that bar-coding is highly accurate and machine-readable information is more reliable than manually entered data (p. 1588, col. 2). Whisler et al. shows that the barcode is readable by scanning (p. 1588, col. 2). Whisler et al. shows the identification mark is an image readable mark (p. 1588, figure 1). Whisler et al. shows that a label having the barcode is affixed to a specimen tube label (p. 1588, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify procedures of processing IVF components of Gianaroli et al. with the use of barcodes in medical specimen processing of

Whisler et al. because Whisler et al. shows that bar-coding is highly accurate and machine-readable information is more reliable than manually entered data.

Response to Arguments

Applicant's arguments filed 15 May 2008 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The combination of Gianaroli et al. in view of Whisler et al. shows a method of controlling the processing of components for *in vitro* fertilization (IVF) using machine readable identification marks. Gianaroli et al. provides methodology presented by the European Society for Human Reproduction and Embryology (ESHRE) for good practices in *In vitro* fertilization laboratories with in the health industry. The methodology or guidelines set forth by the ESHRE provide techniques, procedures and strategies to ensure the highest quality practices in reproductive medicine. Gianaroli et al. provides motivation to increase compliance with the methodology because non-compliance compromises the health and safety of the workers and patients and may result in the loss of gametes and/or embryos. As indicated in the rejection above the element that Gianaroli et al. do not show is a machine readable identification mark of the specimens for *in vitro* fertilization. However, the application of

machine readable identification marks in the health industry is described by Whisler et al. Thus as set forth in the rejection above, one of ordinary skill would have modified the procedures or Gianaroli et al. with the machine readable identification marks of Whisler et al. because Whisler et al. shows machine readable information, such as identification marks and barcodes are highly accurate and more reliable than manually entered data. The motivation provided by Whisler et al. is compatible with the goals of the ESHRE methods of ensuring the highest quality practices in reproductive medicine and would result in a decrease of errors due to manual sample tracking which Whisler et al. estimate to occur at a rate of 10^9 higher than machine tracked samples. The rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571) 272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12 August 2008

/K. R. S./
Examiner, Art Unit 1631
/John S. Brusca/
Primary Examiner, Art Unit 1631